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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,636	11/18/2003	Martin Willard	10527-522001 / 03-257	4327

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MINNEAPOLIS, MN 55440-1022

EXAMINER
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STIGELL, THEODORE J

ART UNIT	PAPER NUMBER
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3763

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/715,636

Applicant(s)

WILLARD ET AL.

Examiner

Theodore J. Stigell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1006/2006, 7/14/2006.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Amendment***

***Double Patenting***

The Double Patenting rejections have been withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining the normal body temperature of a human, does not reasonably provide enablement for determining the normal body temperature of a body. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims are broad enough to read on a method of cooling the body of a snake, bear, shark, or any other animal, which all have different normal body temperatures. There is no disclosure to the normal body temperatures of any animals other than for humans.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is impossible to determine the metes and bounds

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of the claims because "normal body temperature" is an indefinite term, which could be any temperature.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 6-13, 18, and 20-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ginsburg (5,989,238). Ginsburg discloses a method of cooling a target tissue region inside a body, the method comprising providing non-oxygenated fluid (saline solution) cooled below normal body temperature and oxygenated blood (all blood is at least partially oxygenated) at a normal body temperature (the fluid is injected through a catheter into a vessel which has blood of normal body temperature) to the tissue region in proportions to cool the tissue region and maintain, for an extended period of time greater than two minutes, the temperature of the tissue region within a target range between 0-35 degrees Celsius which is 1-9 degrees below normal body temperature, wherein the blood is provided at least once every two minutes, wherein the fluid and blood are provided to the tissue region simultaneously, wherein a catheter provides blood to the tissue by partially occluding a vessel (any device in a vessel

partially occludes the vessel just by being place there) in fluid communication with the tissue region to permit a restricted amount of blood to flow to the tissue region, wherein fluid is provided through the lumen of the catheter, wherein the tissue is maintained within the range of 28 to 36 C for at least two minutes, wherein the delivery can open a lesion in the vessel (drugs are disclosed being delivered), and wherein a control system controls the delivery.

Claims 1-2 and 6-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Dae et al. (6,607,517). See Figures 14-15 and the respective portions of the specification. Dae discloses a method of cooling a target tissue region inside a body, the method comprising providing non-oxygenated fluid (fluid in balloon 262) cooled below normal body temperature and oxygenated blood (all blood is at least partially oxygenated) at a normal body temperature (the blood leading into the heart in Figure 14 is of normal body temperature) to the tissue region in proportions to cool the tissue region and maintain, for an extended period of time greater than two minutes, the temperature of the tissue region within a target range of about 32 degrees Celsius which is 1-9 degrees below normal body temperature, wherein the blood is provided at least once every two minutes, wherein the fluid and blood are provided to the tissue region simultaneously, wherein a catheter provides blood to the tissue by partially occluding a vessel (balloon 262 partially occludes the vessel) in fluid communication with the tissue region to permit a restricted amount of blood to flow to the tissue region, wherein fluid is provided through the lumen of the catheter, wherein the tissue is maintained within the range of 28 to 36 C for at least two minutes, wherein the delivery

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can open a lesion in the vessel, and wherein a control system (270) controls the delivery.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morley et al. (6,113,584). Morley discloses the invention substantially as claimed. Morley discloses to occlude a body vessel and then provide cool fluid to the tissue region and then remove the occlusion to let normal temperature blood into the region. However, Morley does not disclose to repeat the method as is recited in claim 14. It would be obvious to one of ordinary skill in the art at the time of the invention to modify the method of Morley by repeating the method to prevent the temperature of the tissue region from reaching normal body temperature.

***Response to Arguments***

Applicant's arguments with respect to claims 1-25 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Theodore J. Stigell

  
ENCLOSURE  
SUPERVISOR OF PATENT AND TRADEMARKS  
U.S. DEPARTMENT OF COMMERCE